Stratton VA Medical Center IRB Standard Operating Procedure

TITLE: **Revisions to Previously Approved Research**			DOCUMENT NUMBER: **IRB-006**
REVISION NO.: 00	SUPERSEDES/DATE: 00 -	EFFECTIVE DATE: February 5, 2004	PAGE 1 OF 6

IRB CHAIR OR DESIGNEE:	ACOS R&D:	COMPLIANCE:
Signature	Signature	Signature
Name: Ezra Fabricant	Name: Donald Pasquale MD	Name: Yvonne Natale
Date: 1/26/2004	Date: 2-2-04	Date: 2-5-04

1 POLICY

It is Stratton VA Medical Center's policy to comply with all applicable local, state, and federal regulations in the conduct of clinical research studies. Written procedures are required to document review of changes to IRB approved research and to report the IRB's actions to the Principal Investigator.

2 MATERIAL

Protocol Review Request Form for Revision/Amendment
Request for Change in Principal Investigator
Request for Change in Co-investigator/Sub-investigator
Primary Reviewer Form
Notification of Approval with Contingencies
Expedited Review Revision/Amendment Approval letter
Full Committee Final Revision/Amendment Approval letter
Notification of Disapproval letter

3 PROCEDURE

3.1 Principal Investigators may request review of a revision to previously approved research by submitting a Protocol Review Request Form for Revision/Amendment with a copy of all revised documents.

3.1.1 If the amendment addresses an issue related to biosafety, animals, or radiation safety, the appropriate committee or subcommittee must first approve the amendment.

3.2 Upon receipt of the revision request, the Research Office staff stamps it with a date of receipt. The information is reviewed for completeness and accuracy by the IRB staff and is entered into the database.

3.3 If any items are missing or there are questions about the revision, the Principal Investigator or the designated contact person may be contacted by the IRB staff and requested to provide additional information or documents.

3.4 Revisions that represent a minor change may be reviewed by expedited review or may be reviewed by the full IRB. All other changes must be reviewed by the full IRB.

3.4.1 Revisions are minor if the changes do not result in an increase in risk of greater than minimal risk.

3.4.2 The HRPP Coordinator reviews the request, and in consultation with the IRB Chair or designee, recommends whether the research qualifies for expedited review or requires full committee review.

3.5 Expedited Review Process:

3.5.1 A member of the IRB Staff pre-reviews the research. The IRB Chair or designee conducts the review of the revision.

3.5.2 The IRB Chair or designee conducting expedited review has the final authority in deciding whether the revision qualifies for expedited review and may recommend full committee review.

3.5.3 In order to approve revisions covered by this policy, the reviewer shall determine that criteria for approval of research are satisfied as per 38 CFR 16.110 and 16.111.

3.5.4 If the reviewer requests changes or additional information, the IRB staff contacts the Principal Investigator or the designated contact person and requests the information. Upon receipt of the requested information, the changes or additional information are forwarded to the reviewer.

3.5.5 If the reviewer still cannot approve the revision as submitted, the Principal Investigator or designated contact person is notified. The Principal Investigator may modify the research for resubmission to the IRB or resubmit the research for review at a full IRB meeting.

3.5.6 If the reviewer recommends full committee review, the Principal Investigator or designated contact person is notified that the revision must be reviewed by the full committee and is asked to provide additional copies of the research submission.

3.5.7 The reviewer may not disapprove revisions under Expedited Review.

3.5.8 If the reviewer finds the revision acceptable without modifications:

3.5.8.1 The IRB Chair or designee who reviewed the revision approves the revision.

3.5.8.2 The IRB Chair or designee signs and dates the Expedited Review Revision/Amendment Approval letter. This date is the approval date.

3.5.8.3 The Expedited Review Revision/Amendment Approval letter, and approved stamped consent(s), HIPAA authorizations, and assent, if applicable, are sent to the Principal Investigator. A brief description of the revision is included in a parenthetical after the protocol title in the Expedited Review Revision/Amendment Approval letter.

3.5.8.4 The IRB is notified of the approval of the revision in a brief summary in the agenda of the next scheduled IRB meeting.

3.5.8.5 The expiration date of the research remains the same as that of the most recent version approved by the IRB.

3.6 Full Committee Review Process:

3.6.1 Revisions that require full committee review are placed on the agenda of a scheduled IRB meeting. The revision is summarized on the agenda and the agenda identifies all IRB members who are participating in the research to alert the committee to a conflict of interest.

3.6.2 The IRB staff assigns two primary reviewers, who are not participating in the research, based on their area of expertise.

3.6.2.1 The primary reviewers may not be principal investigators or co-investigators of research they are reviewing.

3.6.2.2 The primary reviewers are given a copy of the Protocol Review Request Form for Revision/Amendment, revised or addendum pages from the protocol, and if applicable, revised consent and HIPAA authorization documents, and/or the Investigator Brochure with a summary list of Investigator Brochure changes.

3.6.2.3 Committee Members are given a copy of the revision to review. The revision typically consists of a Protocol Review Request Form for Revision/Amendment, revised or addendum pages from the protocol, and if applicable, revised consent and HIPAA authorization documents and/or a summary list of Investigator Brochure changes. All materials are distributed to committee members approximately two weeks in advance of the meeting.

3.6.2.4 Primary reviewers are provided with a Primary Reviewer Form to record their comments.

3.6.3 The review of revisions takes place at a convened meeting of the IRB.

3.6.4 The IRB staff takes minutes at the meeting pertaining to discussion of the revision.

3.6.5 Minutes are prepared within one week after the meeting and include:

3.6.5.1 Attendance of IRB members at the meeting.

3.6.5.2 The votes for, against, abstaining, recused, and excused. IRB members with a conflicting interest must abstain from voting.

3.6.5.3 Modifications or any other changes to the research required by the IRB.

3.6.5.4 The basis for requiring changes in or disapproving research.

3.6.5.5 A written summary of any discussion of controverted issues and their resolution.

3.6.6 If the revision is approved as submitted,

3.6.6.1 The IRB Chair or designee signs the Final Revision/Amendment Approval letter.

3.6.6.1.1 The Date of Approval is the date of the meeting at which the revisions were approved.

3.6.6.2 The Final Revision/Amendment Approval letter is sent to the Principal Investigator and a copy is sent to the R&D Committee and applicable personnel (i.e. Pharmacy).

3.6.7 If the revision is approved with modifications,

3.6.7.1 The modifications must be documented in sufficient detail to allow the IRB staff to verify the changes required by the IRB.

3.6.7.2 A Notification of Approval with Contingencies, listing all required modifications, is sent to the Principal Investigator.

3.6.7.3 The Principal Investigator responds to the Research Office with a copy of all modified documents.

3.6.7.4 The IRB staff reviews the modified documents for inclusion of all modifications required by the IRB.

3.6.7.5 If the submitted documents have not been modified as required, the Principal Investigator is contacted and asked to submit the complete revision as requested.

3.6.7.6 Once the IRB staff determines that the documents contain all required modifications, the IRB Chair or designee signs the Final Revision/Amendment Approval letter.

3.6.7.6.1 The Date of Approval is the date of the meeting at which the research was approved with modifications.

3.6.7.7 The Final Revision/Amendment Approval letter is sent to the Principal Investigator and a copy is sent to the R&D Committee and applicable personnel (i.e. Pharmacy).

3.6.7.8 If the Principal Investigator does not return the required modified documents within approximately 30 days from the date the letter was issued, the IRB staff notifies the IRB Chair or designee to determine a course of action.

3.6.8 If the revision is disapproved, the IRB staff notifies the Principal Investigator in the Notification of Disapproval letter of the reasons for disapproval and offers the Principal Investigator an opportunity to resubmit the revision to the IRB.

3.7 Revised consents, HIPAA authorizations, and assents associated with modifications are stamped with a Date of Approval and a Date of Expiration. A copy of the stamped consent(s), HIPAA authorizations, assent, and approval letter will be provided to the investigator.

3.7.1 The Date of Approval is defined as the date of the meeting at which the revision was approved.

3.7.2 The Date of Expiration remains unchanged from the original approval, unless a more recent version of the revised document was approved by the IRB.

3.8 The revisions and copies of documents received and sent are filed in the Research Office.

3.9 The IRB staff files the Primary Reviewer Form with the revision/amendment submission.